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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,579	10/27/2000	A. John Bramley	2001796-0006	5413

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,579	BRAMLEY ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 27-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 27-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed May 3, 2004 has been received and entered. New claims 27-44 have been added. Consequently, claims 1-3 and 27-44 are pending in the instant application.

Claim Rejections - 35 USC § 101

1. The rejection of claims 1-3 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-3 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Additionally this rejection is applied to newly added claims 27-44.

Applicants are asserting that the modified genes include a sequence that codes for a lysostaphin protein, the lysostaphin protein differing from a naturally occurring version of lysostaphin produced by a host that naturally produces the lysostaphin protein. Applicants further assert that in contrast to Lilly, the instant application the exact nucleotide sequences of nucleic acids yet to be isolated are not required, provided that the various structural and functional limitations are met. Applicants further assert that the claims have been amended to recite that the claimed DNA encodes a protein which is recognized by a polyclonal antibody that recognizes the naturally

occurring version of lysostaphin. Applicants finally assert that the complete structure of a representative species (i.e., SEQ ID NO: 3) has been provided.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the modified genes include a sequence that codes for a lysostaphin protein, the lysostaphin protein differing from a naturally occurring version of lysostaphin produced by a host that naturally produces the lysostaphin protein. However, as set forth previously, the genus is highly variant because a significant number of structural differences between genus members is permitted. Applicants sole working example of SEQ ID NO: 3, simply does not allow those of skill in the art to recognize a genus of claims based upon this solitary example.

Second, Applicants assert that in contrast to Lilly, the instant application the exact nucleotide sequences of nucleic acids yet to be isolated are not required, provided that the various structural and functional limitations are met. However, this is the exact situation addressed by Lilly. Applicants have provided a mere statement that a modified gene of unknown structure is part of the invention. How is one of ordinary skill in the art to recognize a modified gene when the structure of the unmodified gene remains elusive?

Third, Applicants assert that the claims have been amended to recite that the claimed DNA encodes a protein which is recognized by a polyclonal antibody that recognizes the naturally occurring version of lysostaphin. However, this does not fulfill the requirements of the written description requirements. Applicants will note in the

Examples of the written description guidelines that a function of the protein is sufficient to meet this requirement (e.g., particular enzymatic activity, etc.). Merely reciting that the protein is cross-reactive with an antibody to a different protein does not adequately identify members of the genus by a shared function.

Finally, Applicants assert that the complete structure of a representative species (i.e., SEQ ID NO: 3) has been provided. However, Applicants will note that not a single one of the rejected claims recites this sequence. While this disclosed species meets the written description requirement, it cannot as a single species meet the guidelines for the broadly claimed genus.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a modified gene alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by the modified gene which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai

Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Gagne is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the amended claims:

Claim Rejections - 35 USC § 112

4. Claims 1-3 and 27-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have amended the claims to recite that the protein is "recognized by a polyclonal antibody that recognizes the naturally occurring version of lysostaphin."

Applicants have pointed to support for this limitation at pages 26, 27, 31 and 33. However, the specification refers to the particular modified gene produced by Applicants (i.e., SEQ ID NO: 3) as cross-reacting with polyclonal antibodies to a naturally occurring version of lysostaphin. This does not provide support for claiming ***any*** modified gene which also cross-reacts with polyclonal antibodies to a naturally occurring version of lysostaphin. Accordingly, Applicant is required to demonstrate clear support for the newly filed limitation or cancel the newly added material.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
July 23, 2004